

In re application of  
Gregory M. Fahy  
Application No.: 10/066,285  
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Atty. Dkt. No. 074066-0115

#### REMARKS

In accordance with the present invention, there are provided solutions useful for the liquid state hypothermic preservation of cells, tissues and organs. Invention compositions comprise a combination of polyglycerol and lactose having a total osmotic concentration in the range of 20 milliosmolal to 250 milliosmolal. Also provided herewith are methods for preservation of cells, tissues and organs employing invention compositions.

By the present communication, claims 1-6, 36, 37, 39, 40, 43-49, 51, 59, 61 and 66 have been amended to define Applicant's invention with greater particularity. No new matter is introduced by the subject amendments as the amended claim language is fully supported by the specification and original claims. In addition, by the present communication, claims 67 and 68 have been cancelled without prejudice.

In view of the amendments submitted herewith, claims 1-6, 36-57 and 59-66 are currently pending. A complete listing of the claims, including an indication of the status thereof, is provided in the Listing of Claims beginning at page 2 of this communication.

The provisional rejection of claims 1-6, 36-51, 67 and 68 under the judicially created doctrine of double patenting over claims 6, 18, 21 of co-pending United States Application No. 09/916,396, is respectfully traversed. In view of the provisional nature of this rejection, Applicants defer further action on this issue pending the final disposition of the claims in either of the involved applications.

The rejection of claim 51 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite, is respectfully traversed and has been rendered moot by the amendments submitted herewith. Thus, by the present communication, the objected to terminology ("impermeant" species") has been deleted. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

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The rejection of claims 1-6, 36, 50, 51, 67 and 68 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,194,137 (Khirabadi et al.) in view of United States Patent No. 6,616,858 (Fahy et al.) or (Klebe et al.) *In Vitro*, Vol. 19(3): 167-170 (1983), is respectfully traversed. Applicant's invention, as defined, for example, by claim 1, distinguishes over each of the applied references, taken alone or in combination, by requiring a solution for the liquid state hypothermic preservation of cells, tissues and organs. Invention solutions comprise a combination of polyglycerol and lactose having a total osmotic concentration in the range of 20-250 milliosmolal. None of the cited art discloses or suggests such compositions.

Thus, contrary to the present invention, which is directed to liquid state preservation, Khirabadi et al. is directed to cryopreservation, i.e., solid state preservation. Those of skill in the art readily recognize that hypothermic storage is not cryopreservation, and hypothermic storage solution components are not considered to be cryoprotectants. Cryoprotectants are defined in the scientific literature as being agents that reduce freezing injury. Storage above the freezing point of the solution, as contemplated by the present invention, precludes the occurrence of freezing injury, and thus precludes any solute that may be present from having any cryoprotective effect. Cryoprotective properties are, therefore, completely irrelevant to liquid state storage as contemplated by the present claims. Accordingly, Khirabadi is respectfully submitted to be irrelevant to the present claims.

Further reliance on either of the secondary references is unable to cure the deficiencies of Khirabadi. Klebe, for example, is also directed to cryoprotective agents, and is, therefore, irrelevant to the present claims. Even if Klebe were considered to be relevant, contrary to the Examiner's assertion, the reference actually teaches away from the use of decaglycerol as a cryoprotective agent by demonstrating that decaglycerol is substantially less effective as a cryoprotectant than 18 other alternative cryoprotectants. Thus, no motivation is provided to employ the combination of components required by the present claims.

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Similarly, further reliance on Fahy is also unable to cure the deficiencies of Khirabadi. While Fahy is acknowledged as a significant advance in the art, only the present disclosure teaches the benefits of protective solutions comprising a combination of polyglycerol and lactose. See, for example, Figure 4 of the present disclosure, which demonstrates that the combination of lactose and polyglycerol provides post-operative renal function that is at least twice as good as what was achieved using polyglycerol alone.

In view of the above amendments and remarks, reconsideration and favorable action on all claims is respectfully requested. In the event any issues remain to be resolved in view of this communication, the Examiner is invited to contact the undersigned at the telephone number given below so that a prompt disposition of this application can be achieved.

Respectfully submitted,

Date

9/23/04

By

 EL

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